DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

11 APR 2017

MEMORANDUM FOR ST
ATTN: JANA WARDIAN

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Who's Distressed?: A Comparison of Diabetes-Related Distress by Type of Diabetes and Medication** presented at/published to **Diabetes Care Journal** in accordance with MDWI 41-108, has been approved and assigned local file #**17177.**

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are a 59 MDW staff member, we can forward your request for funds to the designated Wing POC at the Chief Scientist's Office, Ms. Alice Houy, office phone: 210-292-8029; email address: alice.houy.civ@mail.mil.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

Linda Steel-Goodwin

LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

1. The author must complete page two of this form:
   a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D; Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed Medical Research Program (CDMRP) ; Grants; etc.]

   b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.

2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.

3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.

4. Attach a copy of your abstract, paper, poster and other supporting documentation.

5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.

6. On page 2, have either your unit commander, program director or immediate supervisor:
   a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.

7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). **This should be accomplished no later than 30 days before final clearance is required to publish/present your materials.** If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.

8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.

9. Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. **Note:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.

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11. The Joint Ethics Regulation (JER) DoD 5500.07-R, *Standards of Conduct*, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. **If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review.** To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

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NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:
"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:
"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401_IP :
"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Jana Wardian, Ctr, 59MDSP	☐ YES ☒ NO	FWH20170001H

5. PROTOCOL TITLE: (**NOTE:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)
Using the Diabetes-Related Distress Scale in Clinical Practice

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:
Who's Distressed?: A Comparison of Diabetes-related Distress by Type of Diabetes and Medication

7. FUNDING RECEIVED FOR THIS STUDY? ☐ YES ☒ NO FUNDING SOURCE:

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☒ YES ☐ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO **NOTE:** If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☒ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)
Diabetes Care

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☐ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)

☐ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)

☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. HAVE YOUR ATTACHED RESEARCH/TECHNICAL MATERIALS BEEN PREVIOUSLY APPROVED TO BE PUBLISHED/PRESENTED?
☐ YES ☒ NO ASSIGNED FILE # _____ DATE _____

13. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE	
April 10, 2017	

14. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	15. DUTY PHONE/PAGER NUMBER
Wardian, Jana, L. Jana.L.Wardian.ctr@mail.mil	554-5037

16. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Jana Wardian	CTR	59MDSP/SGME	
b. Joshua Tate	CAPT	59 MDOS/SGO5E	BAMC
c. Irene Folaron	LT COL	59 MDOS/SGO5E	BAMC
d. Sky Graybill	MAJ	59 MDOS/SGO5E	BAMC
e. Mark True	COL	59 MDOS/SGO5E	BAMC

17. IS A 502 ISG/JAC ETHICS REVIEW REQUIRED (JER DOD 5500.07-R)? ☐ YES ☒ NO

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

18. AUTHOR'S PRINTED NAME, RANK, GRADE	19. AUTHOR'S SIGNATURE	20. DATE
Jana Wardian, CTR	WARDIAN.JANA.L.1515244472	March 31, 2017
21. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	**22. APPROVING AUTHORITY'S SIGNATURE**	**23. DATE**
Tom Sauerwein, CIV	SAUERWEIN.TOM.J.1174239947	March 31, 2017

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	24. DATE RECEIVED March 31, 2017	25. ASSIGNED PROCESSING REQUEST FILE NUMBER 17177
26. DATE REVIEWED April 07, 2017	27. DATE FORWARDED TO 502 ISG/JAC	

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29. COMMENTS ☒ APPROVED ☐ DISAPPROVED

Presentation of IRB approved research with appropriate disclaimers. Approved

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	31. REVIEWER SIGNATURE	32. DATE
Kevin Kupferer/GS13/Human Research Subject Protection Expert	KUPFERER.KEVIN.R.1086667270	April 07, 2017

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42. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	43. REVIEWER SIGNATURE	44. DATE
Kevin Iinuma, SSgt/E-5, 59 MDW Public Affairs	IINUMA.KEVIN.MITSUGU.1296227613	April 10, 2017

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	Jana Wardian, Ctr, 59MDSP	☐ YES ☒ NO	FWH20170001H

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Diabetes Care

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Wardian, Jana, L. Jana.L.Wardian.ctr@mail.mil	554-5037

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LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Jana Wardian	CTR	59MDSP/SGME	
b. Joshua Tate	CAPT	59 MDOS/SGO5E	BAMC
c. Irene Folaron	LT COL	59 MDOS/SGO5E	BAMC
d. Sky Graybill	MAJ	59 MDOS/SGO5E	BAMC
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29. COMMENTS ☒ APPROVED ☐ DISAPPROVED

Presentation of IRB approved research with appropriate disclaimers. Approved

30. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	31. REVIEWER SIGNATURE	32. DATE
Kevin Kupferer/GS13/Human Research Subject Protection Expert	KUPFERER.KEVIN.R.1086667270	April 07, 2017

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47. COMMENTS ☐ APPROVED ☐ DISAPPROVED

48. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	49. REVIEWER SIGNATURE	50. DATE

Who's Distressed?:

A Comparison of Diabetes-related Distress by Type of Diabetes and Medication

Jana L. Wardian, PhD[1]
Joshua Tate, MD[2]
Irene Folaron, MD[2]
Sky Graybill, MD[2]
Mark True, MD[2]
Tom Sauerwein, MD[1]

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Word Count: 2082
Tables: 3
Figures: 1

Abstract

Objective: We hypothesized that total diabetes-related distress (DRD) would vary by type of diabetes and medication regimen [Type 1 diabetes (T1DM), Type 2 diabetes with insulin use (T2DM-i), Type 2 diabetes without insulin use (T2DM)]. Thus, the aim of this study is to identify those groups with elevated DRD.

Research Design and Methods: The Diabetes Center of Excellence administered the 17-item Diabetes-related Distress Scale (DDS-17) to 585 patients as part of standard care. In addition, we collected demographics, medications, vital signs, and lab results.

Results: Patients were categorized by type of diabetes and medication: T1DM (n=149); T2DM-i (n=333); and T2DM (n=103). Two-way ANOVA revealed significant differences in total DDS-17; T1DM (M=1.62, SD=0.66) had significantly lower DDS-17 than T2DM-i (M=1.82, SD=0.80), $p<.05$. In addition, emotional burden (EB) was significantly lower in T1DM (M=1.88, SD=1.00) than T2DM-i (M=2.13, SD=1.17), $p<.05$. Regimen-related distress (RD) was significantly lower in T1DM (Mean=1.85, SD=.96) than T2DM-i (M=2.16, SD=1.10), $p<.05$. Relatively few patients scored high in physician-related distress (PD) (4.4%). Highest levels of interpersonal distress (ID) were found in patients with T2DM-i (8.4%) and T1DM (8.1%).

Conclusions: Overall DDS-17 was highest for T2DM-i. Our findings suggest that high EB is closely associated with insulin therapy; T1DM and T2DM-i were highest in EB (15.4% and 20.1%), respectively. Nearly 1 in 5 people with T2DM-i or T2DM were likely to have RD, which suggests that activities associated with self-management are more challenging for those with type 2 diabetes.

Who's Distressed?:

A Comparison of Diabetes-related Distress by Type of Diabetes and Medication

Background:

Managing diabetes is not easy. Polonsky et al. (2005) describes diabetes as a "complex, demanding, and often confusing set of self-care directives" in which "patients may become frustrated, angry, overwhelmed, and/or discouraged" (p. 626). The American Diabetes Association (ADA) recommends psychosocial assessment as an integrated part of routine care for people with diabetes (PWD) (Young-Hyman, 2016).

The concept of diabetes-related distress (DRD), which encompasses patients' concerns about self-care, support, emotional burden, and quality of healthcare, is a common challenge for PWD (Fisher et al., 2008; Polonsky et al., 2005). While depression is prevalent in PWD, DRD has been found to be even more common, with a prevalence of 18-35% (Fisher et al., 2007; Fisher et al., 2010). DRD is noted to be a separate clinical entity, whereby about 70% of patients with identified DRD were not clinically depressed (Fisher et al., 2007; Fisher et al., 2012). DRD can be assessed using the 17-item Diabetes-related Distress Scale (DDS-17), which measures DRD in four distinct domains: 1) emotional burden (EB); 2) physician-related distress (PD); 3) regimen-related distress (RD); and 4) interpersonal distress (ID) (Table 1) (Young-Hyman, 2016; Fisher, 2008; Polonsky, 2005).

Elevated DRD has been shown to have a negative impact on self-management, medication adherence, and quality of life (Fisher, 2009). A significant time-concordant relationship to HbA1c has been noted, with higher HbA1c values correlating to higher DRD levels (Fisher, 2010). The opposite has also been shown, as lower DRD levels are associated with patient self-efficacy and physician support (Wardian & Sun, 2014). Despite knowing the relationship of DRD to diabetes-related health outcomes, the relationship to type of diabetes and

medication regimen has not been evaluated in a diabetes clinic setting. This study sought to explore these factors as they relate to high DRD, as measured by DDS-17, in a diabetes clinic setting. We hypothesized that DDS-17 would significantly vary by type of diabetes and medication regimen [Type 1 diabetes (T1DM), Type 2 diabetes with insulin use (T2DM-i), Type 2 diabetes without insulin use (T2DM)]. The goal of our study was to identify those groups with elevated DRD, which would enable a targeted intervention to decrease DRD.

Research Design and Methods

Wilford Hall Ambulatory Surgical Center Institutional Review Board approval was obtained for this retrospective data analysis. Data were collected at the Diabetes Center of Excellence (DCOE) through chart reviews of clinical visits from June 2015 through August 2016. The DCOE is an Air Force diabetes specialty clinic treating complex cases of diabetes including patients with type 1 diabetes (T1DM) and patients with multiple co-morbidities. Our population consists of all branches of active duty military, retired, and family members. The DCOE began administering the 17-item Diabetes-related Distress Scale (DDS-17) in June 2015 as standard care (Table 1).

Inclusion criteria were adult patients (19 and older) with diabetes receiving their diabetes care at the DCOE. Data were stored on military computers that were password and firewall protected. As part of the regular patient visit, patient responses to the DDS-17 were recorded by licensed vocational nurses (LVNs). All patients completed a DDS-17 as part of the clinical visit (N=585). DDS-17 scores were categorized as: <2.0 = little or no distress; 2.0-2.9 = moderate DRD; and ≥ 3 = high DRD. In addition, there are four domains that represent distinct areas of DRD: 1) Emotional Burden (EB); 2) Physician-related Distress (PD); 3) Regimen-related Distress (RD); and 4) Interpersonal Distress (ID) (Fisher et al., 2012).

After input, the *NoteWriter,* an Excel-based clinical note writing platform, calculated scores for total DDS and each subscale. Figure 1 shows the *NoteWriter*, DDS-17 total and subscale scores with associated level of distress designated by a color-coded radial button on the dashboard: green <2.0=little or no distress; yellow between 2.0-2.9=moderate DRD; or red ≥3 signaled high DRD, which are consistent with cut points established by Fisher et al. (2012). The area(s) designated as yellow or red were further explored by the provider to determine the source of the DRD and collaborate with the patient to determine strategies to reduce the associated distress.

In addition to the DDS-17, data included patient demographics (gender, age, ethnicity/race, rank, military status), vital signs (blood pressure, weight, etc.), and lab results (comprehensive metabolic panel including HbA1c).

Results

A total of 610 DCOE patients completed a baseline DDS-17 from June 2015 through August 2016. However, 25 patients were categorized as "other" type of diabetes, which left 585 patients that could be categorized as 1) Type 1 diabetes (T1DM); 2) Type 2 diabetes on insulin therapy (T2DM-i); or 3) Type 2 diabetes not on insulin therapy (T2DM).

Table 2 provides a comparison of demographic and clinical markers for the 585 patients included in this study. There were slightly more men than women represented in the data. Patients with T1DM were youngest (46.01) and younger age at diagnosis (26.50). Duration of diabetes was highest in T1DM (20.09 years) followed by T2DM-i (16.91 years) and T2DM (9.09 years). Overall, 43.3% of the sample were White; 21.6% were African American; and 27.5% Hispanic/Latino. The highest concentration of Whites were in the T1DM category (63.5%).

Military rank included both active duty and retired members and was evenly distributed within the T1DM category, but in the T2DM-i and T2DM groups, senior enlisted represented

about 40% of the sample. Family members accounted for about two-thirds of the T1DM group and about 40% of the Type 2 DM groups.

T1DM and T2DM-i groups were on insulin therapy. Few patients in the T1DM were taking an additional DM medication. However, most of the patients in the T2DM-i group were taking one (34.1%) or two (36.0%) additional diabetes medications. Patients in the T2DM group were taking oral medications for their diabetes. The most common oral diabetes medication was metformin; overall 52.5% of those with T2DM-i and T2DM were taking metformin.

Clinical measures included BMI and HbA1c. Both were lowest in the T1DM group, followed by the T2DM group and highest in T2DM-i patients.

Total DDS-17 and DDS-17 subscales were subjected to two-way analysis of variance (ANOVA) to assess differences in means between and among groups (Table 3). Significant differences were found in total DDS-17; those with T1DM (M=1.62, SD=0.66) had significantly lower total DDS-17 than T2DM-i (M=1.82, SD=0.80), $F(2, 582)=4.13$, $p<.05$. In addition, those with T1DM (M=1.88, SD=1.00) had significantly lower EB than T2DM-i (M=2.13, SD=1.17), $F(2, 582)=3.88$, $p<.05$. Those with T1DM (Mean=1.85, SD=.96) had significantly lower RD than T2DM-i (M=2.16, SD=1.10), $F(2, 582)=4.33$, $p<.05$.

Relatively few patients scored high in PD (26 patients; 4.4%); however, highest PD was found in the T2DM group (6.8%). The highest levels of ID were found in patients on insulin therapy, T2DM-i (8.4%) and T1DM (8.1%).

Conclusions

Our results demonstrate that EB and RD have the greatest contribution to DRD among all the DM groups in our study. Overall, PD contributed the least to DRD. Identifying EB and RD

as the dominant sources of DRD facilitates targeted intervention and modifications in our patient-centered encounters to reduce these sources of distress.

Several limitations must be noted due to our distinctive population and generalizability must be done with caution. The DCOE is an Air Force diabetes specialty clinic, which exclusively treats Department of Defense (DoD) beneficiaries. Thus, access to healthcare differs from a civilian population. Notably, there is no cost for healthcare including pump supplies, medication, and blood sugar monitoring supplies. This may influence DRD in a number of ways. One could argue that this benefit would reduce DDS-17 across all domains; however, along with essentially free healthcare come limited choice in providers and reduced options, as some medications are not included on the formulary. In addition, some of our patients travel long distances to receive care at the DCOE, which could be an additional stressor.

The percentage of PWD scoring high in total DDS in our patient population was lower than in many other studies. About 7.0% of our patients scored high in total DDS-17. While high DDS was found in 4.0%-18.7% of primary care PWD (Delahanty et al., 2007; Kuniss et al., 2017; Stoop et al., 2014). Patients seen in secondary care clinics like the DCOE were considerably higher with 19.0% of PWD scoring high in DDS (Stoop et al., 2014).

EB was highest among our participants on insulin therapy (T1DM and T2DM-i) and existing literature provides insight into this association. Self-care requirements, perception of higher disease severity, physical discomfort of injections, and fear of hypoglycemia and other complications are cited as unique sources of emotional burden for those taking insulin (Gray et al., 2017; Jones et al., 2015). Even the thought of insulin has been associated with high EB for those who do not yet require insulin. Patients appear to view insulin as a sign of failure in self-care and a forecast of reduced flexibility in life (Holmes-Truscott et al., 2015; Holmes-Truscott

et al., 2016). The negative appraisal of insulin and the high EB that result are important insights for the provider in order to design diabetes education and shared decision-making towards meaningful and mutual clinical goals.

Our study indicates that people on insulin therapy, T1DM and T2DM-i, were highest in EB (15.4% and 20.1%), respectively. The emotional toll of diabetes, especially for those on insulin therapy, is arduous. EB was the leading cause of distress for those who reported high levels of distress, particularly those taking insulin, which is consistent with other studies (Gray et al., 2017; Jones et al., 2015; Ramkisson et al., 2016). Our findings suggest that high EB is closely associated with insulin therapy; existing literature supports this notion. Self-care requirements, perception of higher disease severity, physical discomfort of injections, and fear of hypoglycemia and other complications are cited as unique sources of emotional burden for those taking insulin (Gray et al., 2017; Jones et al., 2015).

Conversely, those with high EB, whether or not they are already on insulin, are found to have negative appraisals of insulin therapy. For the T2DM group not on insulin, EB was the second leading cause of DRD after RD. Patients appear to view insulin as a sign of failure in self-care and a forecast of reduced flexibility in life (Holmes-Truscott et al., 2015; Holmes-Truscott et al., 2016). Since the DCOE is a diabetes specialty clinic and cares for patients with more complex diabetes, our patients with T2DM may be experiencing increased anxiety about the possibility of initiating insulin therapy if their diabetes cannot be effectively managed on non-insulin medications.

Insulin therapy is one factor in EB, but EB seems to be a more comprehensive construct. In totality, other forms of DRD feed into a patient's emotional burden. For example, a survey study among ethnically diverse patients with T2DM found that culturally competent

communication and trust in their physicians, a factor in PD, were associated with lower EB (Slean et al., 2012). Additionally, the perception of low social support, a factor in ID, was associated with higher EB (Joensen et al., 2015). Our population reported relatively low levels of PD and ID. Therefore, our results would suggest that EB in our population is attributable to insulin requirement, hence the higher EB scores among our T1DM and T2DM-i participants.

An important finding in this study is that people with T2DM-i were more likely to have RD than people with T1DM. People with T1DM require insulin upon diagnosis, but many people with type 2 diabetes manage diabetes with lifestyle adjustments and/or non-insulin regimens for a period of time (ADA, 2017), which may make adding insulin management more complex by comparison. Patients with type 2 diabetes may additionally experience a sense of guilt that they are responsible for the disease progression, which may be compounded by a sense of failure if they require insulin (Benroubi, 2011; Delahanty, 2007; Phillips, 2005).

Furthermore, people with type 2 diabetes often have co-occurring conditions (ie hypertension, dyslipidemia, cardiovascular disease), which require additional medications (ADA, 2017). Logically, patients are more adherent to simple medication regimens compared to complex ones (Osterberg & Blaschke, 2005); thus, a reasonable conclusion is that simpler medication regimens would induce less RD. However, this over simplifies RD as medication dosing is only one factor than can contribute to RD. All patients with diabetes share challenges with their multifaceted management regimens, which include blood sugar monitoring, timing of medication with meals, and concerns about extremes in blood sugar as a consequence of intentional or unintentional non-adherence to any aspect of the regimen.

We found that the vast majority of our patients had low levels of PD, 94.0% in the T1DM group, 90.7% in the T2DM-i group, and 87.4% in the T2DM group, with no statistical difference

between the three groups. We attribute this finding to several causes. Primarily, we conducted the study at the DCOE, a specialty center where patients receive care from endocrinologists or from providers who are closely supervised by endocrinologists. A patient is less likely to have a concern about a provider's diabetes knowledge in our center as compared to a primary care clinic.

Additionally, the DCOE embraces a multidisciplinary approach to each patient encounter such that several individuals interact with the patient (Sauerwein, 2015). Before the visit, medical assistants review the patient record to identify any issues or upcoming deadlines to meet diabetes standard of care. During the visit, they also perform a structured patient intake, medication reconciliation, and perform foot examinations when due. Their actions enable providers to be more focused on patient concerns and treatment plans during their portion of the encounter. Certified diabetes educators (CDEs) are subsequently available after the provider visit to reinforce the plan and perform additional teaching regarding how to use new equipment (e.g., insulin pens, continuous glucose monitors, insulin pumps, etc.).

A patient-centered approach is central to the DCOE philosophy. The concepts of motivational interviewing and shared-decision making are discussed, reviewed, and taught by staff on a regular basis. It is, therefore, very unusual for a patient to voice a complaint that his or her concerns are unheard or not taken seriously. Finally, the DCOE support staff members make themselves available to patients between provider visits by inviting phone calls to the clinic, communication via the secure messaging system, or additional CDE encounters as needed to address concerns. Concerns that cannot be addressed by support staff are elevated to the providers.

DDS is an important psychosocial aspect of care for PWD. Assessing DDS on a regular basis is consistent with standards of diabetes care (ADA, 2017). Understanding who may be experiencing DDS and where the source of the distress is located assists providers in tailoring interventions to reduce DDS; thus, enabling patients to better engage in self-management and reach their treatment goals.

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Author Contributions:
Dr. Wardian contributed to the methods, conducted the analysis, and reviewed/edited the manuscript.
Dr. Tate contributed to the background, assisted with analysis, and reviewed/edited the manuscript.
Dr. Folaron contributed to the conclusions and reviewed/edited the manuscript.
Dr. Graybill contributed to the conclusions and reviewed/edited the manuscript.
Dr. True contributed to the conclusions and reviewed/edited the manuscript.
Dr. Sauerwein assisted with analysis, contributed to the conclusions and reviewed/edited the manuscript.

Diabetes Distress Scale

Question	
1	1
2	4
3	3
4	2
5	1
6	4
7	3
8	5
9	1
10	2
11	4
12	4
13	2
14	4
15	1
16	4
17	3

Total DDS **PRIOR DDS**

2.8

Emotional Burden

3.4

Physician-related Distress

2

Regimen-related Distress

3

Interpersonal Distress

2.7

Figure 1. *NoteWriter* Dashboard DDS-17 Total and Subscales

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Table 1. The 17-item Diabetes-related Distress Scale (DDS-17)

Emotional Burden (EB)

1. Feeling that diabetes is taking up too much of my mental and physical energy every day.
2. Feeling angry, scared, and/or depressed when I think about living with diabetes.
3. Feeling that diabetes controls my life.
4. Feeling that I will end up with serious long-term complications, no matter what I do.
5. Feeling overwhelmed by the demands of living with diabetes.

Physician-related Distress (PD)

1. Feeling that my doctor doesn't know enough about diabetes and diabetes care.
2. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.
3. Feeling that my doctor doesn't take my concerns seriously enough.
4. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.

Regimen-related Distress (RD)

1. Feeling that I am not testing my blood sugars frequently enough.
2. Feeling that I am often failing with my diabetes.
3. Not feeling confident in my day-to-day ability to manage diabetes.
4. Feeling that I am not sticking closely enough to a good meal plan.
5. Not feeling motivated to keep up my diabetes self-management.

Interpersonal Distress (ID)

1. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).
2. Feeling that friends or family don't appreciate how difficult living with diabetes can be.
3. Feeling that friends or family don't give me the emotional support that I would like.

Responses are on a 6 point continuum from 1=Not a problem; 2=A slight problem; 3=A moderate problem; 4=Somewhat serious problem; 5=A serious problem; 6=A very serious problem

Table 1. Sample Characteristics by Type of Diabetes and Medication Regimen

	T1DM		T2DM-i		T2DM	
	n	%	n	%	n	%
	149	25.5%	333	56.9%	103	17.6%
Sex						
Female	82	45.0%	141	42.3%	43	41.7%
Male	67	55.0%	192	57.7%	60	58.3%
Mean Age	46.01	-	59.87	-	53.34	-
Age at Diagnosis	26.50	-	43.22	-	45.57	-
Duration of Diabetes	20.09	-	16.91	-	9.09	-
Ethnicity/Race						
White	94	63.5%	127	38.4%	31	30.1%
African American	30	20.3%	73	22.1%	23	22.3%
Hispanic/Latino	16	10.8%	106	32.0%	38	36.9%
Asian/Pacific Islander	8	5.4%	22	6.6%	8	7.8%
Military Rank						
Junior Enlisted	15	30.6%	76	39.8%	22	38.6%
Senior Enlisted	17	34.7%	89	46.6%	27	47.4%
Officer	17	34.7%	26	13.6%	8	14.0%
Military Status						
Active Duty	14	9.6%	10	3.0%	10	9.7%
Retired	36	24.7%	182	55.3%	48	46.6%
Family Member	96	65.8%	137	41.6%	45	43.7%
Other Medications						
Metformin	10	7.1%	174	54.2%	55	53.4%
DPP4 Inhibitor	1	0.7%	62	19.6%	13	12.6%
GLP-1 Agonist	5	3.6%	127	39.7%	24	23.3%
Sulfonylurea	0		9	2.9%	23	22.3%
BMI	28.48	-	33.86	-	31.15	-
Current HbA1c	8.00%	-	8.38%	-	8.30%	-

T1DM=Type 1 diabetes; T2DM-i=Type 2 diabetes on insulin therapy; T2DM=Type 2 diabetes not on insulin therapy

Table 3. Diabetes-related Distress (DDS) by Type of Diabetes and Medication Regimen

	T1DM		T2DM-i		T2DM		*p* value
	n	%	n	%	n	%	ANOVA
	149	25.5%	333	56.9%	103	17.6%	
Total DDS-17* (n=585)							0.02
Low	115	77.2%	234	70.3%	76	73.8%	
Moderate	27	18.1%	70	21.0%	22	21.4%	
High	7	4.7%	29	8.7%	5	4.9%	
Emotional Burden (EB)*							0.02
Low	96	64.4%	182	54.7%	62	60.2%	
Moderate	30	20.1%	84	25.2%	29	28.2%	
High	23	15.4%	67	20.1%	12	11.7%	
Physician-related Distress (PD)							0.30
Low	140	94.0%	301	90.7%	90	87.4%	
Moderate	6	4.0%	15	4.5%	6	5.8%	
High	3	2.0%	16	4.8%	7	6.8%	
Regimen-related Distress (RD)*							0.01
Low	98	65.8%	177	53.2%	59	57.3%	
Moderate	35	23.5%	91	27.3%	25	24.3%	
High	16	10.7%	65	19.5%	19	18.4%	
Interpersonal Distress (ID)							0.20
Low	123	82.6%	259	77.8%	89	86.4%	
Moderate	14	9.4%	46	13.8%	8	7.8%	
High	12	8.1%	28	8.4%	6	5.8%	
PHQ-9 (n=298)	77	25.8%	183	61.4%	38	12.8%	0.22
Positive for depression	8	10.4%	24	13.1%	3	7.9%	

T1DM=Type 1 diabetes; T2DM-i=Type 2 diabetes on insulin therapy; T2DM=Type 2 diabetes not on insulin therapy

*$p<.05$